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June 19, 2000

Mr. Jere W. Glover, esq.
Chief Counsel for Advocacy
U.S. Small Business Administration
Washington, D.C. 20416

Dear Mr. Glover:

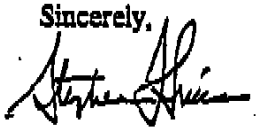
I am writing on behalf of my client, the Pharmaceutical Distributors Association, to thank your office for its timely and effective intervention on behalf of small businesses in a rulemaking by the Food and Drug Administration relative to the Prescription Drug Marketing Act. In December, 1999 the FDA issued a Final Rule completing the implementation of this 1988 statute. The effective date of the Rule was December 4, 2000.

By the FDA's own calculation, some 4,000 pharmaceutical distributors who are small businesses are covered by the rule. The FDA's regulatory impact analysis, which was seriously flawed, concluded that the rule would have no impact on these companies. In fact, the rule would drive most of them out of business, threatening the supply of pharmaceuticals to end users and placing upward pressures on drug prices.

You and Shawn Carter McGibbon, the Assistant Chief Counsel for Advocacy, drafted a letter to the FDA Commissioner on February 29, 2000 asking that agency to reconsider its Final Rule, suspend the effective date and reissue regulations more in keeping with the intent of the Congress. This letter, and the detailed analysis therein, played a major role in convincing the FDA to reopen the Final Rule for further comments and extend its effective date to October 1, 2001.

The Office of Advocacy's intervention in this matter is a valuable case study in the need for small businesses to have a Federally established oversight organization to whom they can appeal in cases where agency impact analyses are seriously flawed. Thank you again for the very timely and effective work of you office in this important economic and policy matter.

Sincerely,



Stephen F. Sims
Pharmaceutical Distributors Association

cc: Mr. Sal Ricciardi, PDA